REMARKS

Status of the Claims

Claims 40-61 are currently pending in the present application. Claims 1-39 have been canceled without prejudice or disclaimer of the subject matter claimed therein. New claims 45-61, directed to the same invention as claims 1, 2, and 27-39, have been added. Claims 40-44 are withdrawn from examination as being directed to a separate invention.

Amendment to the Claims

Claims 40 and 44 (withdrawn) have been amended to correct their dependencies.

New claims 45-61 have been added. Support for new claims 45-61 can be found throughout the specification. Representative support is summarized in the table below. New claims 45-61 do not introduce prohibited new matter.

Claims	Support
45	Claim 1; Page 13, lines 6-9
46	Claim 2
47	Claim 27
48	Claim 28
49	Claim 29
50	Claim 30; Page 20, lines 5-7
51	Claim 31
52	Claim 32
53	Claim 33
54	Claim 34
55	Claim 35
56	Claim 36
57	Claim 37
58	Claim 38
59	Claim 39
60, 61	Page 16, lines 6-13

Rejection Under 35 U.S.C. § 102(b)

Claims 1, 2, 27-35 and 37-39 are rejected under 35 U.S.C. § 102(b) as being anticipated by Kozwich *et al.* (U.S. Patent No. 6,153,425 ('425)).

Claims 1, 2, 27-35, and 37-39 have been canceled and replaced with new claims 45-61. Claim 45 includes the following features: (1) both the extraction zone and the amplification zone are located on a porous matrix; (2) the associated extraction and amplification steps are thus performed in or on a porous matrix; and (3) the liquid sample applied to the device flows along the porous matrix passing sequentially through the extraction zone and amplification zone to the detection zone by means of capillary action, through the porous matrix. Claims 46-61 are dependent upon claim 45 and therefore, include the features described above.

The Office Action alleges that '425 teaches a self-contained lateral flow assay device to test for the presence and/or the amount of a nucleic acid sequence of interest in a sample. Applicants respectfully submit that the device of '425 do not include all the features recited in the claims.

Applicants respectfully point out that claim 45 is drawn to a lateral flow assay device and that the device disclosed by '425 is not a lateral flow device. The device disclosed by '425 utilizes, as part of the device, a lateral flow test strip for the final detection step, but it also comprises many other features and components. As such, a person having ordinary skill in the art would not understand the assay device disclosed by '425 to be a "lateral flow assay device." In contrast, the device of the present invention is a lateral flow device. As described on page 2 (last paragraph) of the specification, lateral flow devices typically utilize a single, capillary device or porous carrier that contains the reagents necessary for the performance of an assay. Thus, the lateral flow assay device of the present invention is much simpler than, and structurally very different from that disclosed by '425. As mentioned, the device of '425 is not a lateral flow device as understood by the person having ordinary skill in the art.

Moreover, present claim 45 requires that the sample applied to the device flows along the device, from sample application region to (ultimately) the detection zone, by capillary action. This is also implicit in the term "lateral flow assay device." Although in the device of '425, there is capillary flow of the sample from the upper cylinder 2 (in Figure 1) into the lower

cylinder, by means of an absorbent pad (9), into the porous detection membrane (10), there is no disclosure in '425 of capillary flow from an extraction zone, to an amplification zone and hence to a detection zone. Rather, there is only disclosure of capillary flow from a combined extraction/amplification zone, which is non-porous, to a detection zone.

Further, the present invention provides, for the first time, a lateral flow assay device, in which extraction, nucleic acid amplification, and detection all take place on a porous matrix. The resulting integrated device is far simpler to make and use than the device disclosed by '425. The present inventors have in particular appreciated that the extraction step could be performed on a porous matrix, within the context of an assay device, and that this could be utilized to construct a true lateral flow assay device, with the associated advantages of lateral flow assays.

Applicants also point out that in '425, the extraction step always occurs in suspension. For instance, in Example 1 (column 9) of '425, the sample is added to cylinder 2 which contains the lysing reagents for nucleic acid extraction. Thus in '425, only after the nucleic acid has been extracted, does it become bound to a solid phase or silica slurry, neither of which is necessarily a porous matrix. Moreover, in Example 5 of '425, the amplification step is performed in suspension. In contrast, the presently claimed invention requires that the extraction zone and the amplification zone be located on a porous matrix.

Applicants respectfully submit that the claimed invention requires that one or more reagents required to perform the nucleic acid amplification step be releasably bound to the porous matrix (new claim 48). In rejecting this claim, the Office Action refers to column 9, lines 40-47 and column 11, lines 29-36 of '425. However, column 9 teaches that the amplification enzymes are releasably bound to "reaction bead 11". '425 does not teach that the reaction bead is a porous matrix. Further, the amplification is said to take place "on the solid phase 22 or silica slurry 23", not on the reaction bead 11. Thus, reaction bead 11, even if it were porous (which is not stated in '425) is not the porous matrix on which the amplification step takes place. In contrast, the claims as they stand require that the amplification be located on the porous matrix.

Moreover, new claim 53 requires that the lateral flow device comprises "dodecyl triethyl ammonium bromide or FTA paper." '425 does not appear to disclose or suggest such reagents on a matrix.

Further, the claimed invention requires that the assay device comprises means for altering the relative positions of two or more portions of the porous matrix, so as to affect the rate of flow of liquid from one portion to another (new claim 55). The Office Action alleges that '425 discloses this feature because it teaches that microparticles can be located in different positions on the porous matrix. It is not understood what "means" is disclosed by '425 to do this, how this alters the relative positions of two portions of the porous matrix, or how this affects the rate of flow of liquid from one portion to the other. Applicants respectfully request reconsideration of this rejection in view of the amendment to claim 45.

New claims 60 and 61 are directed to particular preferred embodiments of the invention which are not disclosed or suggested by '425. There is no disclosure or suggestion in '425 of a porous matrix (comprising cellulose, a cellulose derivative or nylon) which contains both an extraction zone and a nucleic acid amplification zone, or which is provided with a backing material.

Accordingly, since '425 neither teaches nor suggests the claimed invention, '425 does not anticipate or render the claimed invention obvious.

Rejection Under 35 U.S.C. § 103

Claim 36 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Kozwich *et al.* (U.S. Patent 6,153, 425 ('425)) in view of Cardy *et al.* (WO 93/06240 ('240)).

Claim 36 has been canceled and replaced with claim 56. The cited references do not render claim 56 obvious because the cited references do not disclose or suggest all the features of the claimed invention.

The deficiencies of '425 have been discussed immediately above in detail. '240 has been cited for teaching SMART amplification. However, '240 does not cure the deficiencies of '425. As acknowledged by the Office Action, '240 does not teach a self-contained lateral flow device for detecting the present and/or amount of nucleic acid sequence in a sample comprising sample receiving, extracting, amplification, and detection zones. Moreover, '240 does not teach or suggest that both the extraction zone and the amplification zone are located on a porous matrix, that the associated extraction and amplification steps are thus performed in/on a porous matrix, and that the liquid sample applied to the device flows along the porous matrix passing

sequentially through the extraction zone and amplification zone to the detection zone, by means of capillary action, through the porous matrix.

Accordingly, there is no motivation to combine the teachings of '425 and '240 and to modify the teachings in order to obtain the claimed invention with reasonable expectation of success. Thus, the cited references, '425 and '240, do not render the claimed invention obvious.

Conclusion

The foregoing amendments and remarks are being made to place the application in condition for allowance. Applicants respectfully request entry of the amendments, reconsideration, and the timely allowance of the pending claims. A favorable action is awaited. Should an interview be helpful to further prosecution of this application, the Examiner is invited to telephone the undersigned.

If there are any additional fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-0310. If a fee is required for an extension of time under 37 C.F.R. §1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,
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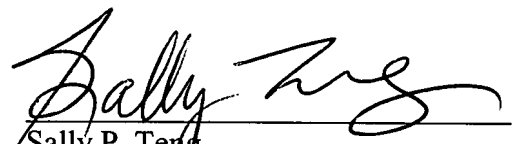

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